UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CARL JOHAN FRIDDLE,
BRENDA GERHARDT and D. WADE WALKE

Appeal No. 2005-1923
Application No. 09/916,122

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-5, all of the claims in the application. Claim 1 is representative and reads as follows:

1. An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2.

The examiner does not rely on any references:

Claims 1-5 stand rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as lacking patentable utility.

We affirm.

Background

"[M]embrane receptor proteins are often involved in transduction pathways that control cell physiology, chemical communication, and gene expression. A particularly relevant class of membrane receptors are those typically characterized by the presence of 7 conserved transmembrane domains. . . . Such, '7TM receptors' include a superfamily of receptors known as G-protein coupled receptors (GPCRs)." Specification, pages 1-2. "The present invention relates to the discovery, identification, and characterization of nucleotides that encode a novel GPCR and the corresponding novel GPCR amino acid sequence. The GPCR . . . is a transmembrane proteins [sic] that spans the cellular membrane and is involved in signal transduction after ligand binding." Page 2.

The specification does not say what ligand binds to the disclosed GPCR, or what signal is putatively transduced by the protein, or what role the protein plays in any physiological process. Nonetheless, the specification discloses that the protein of SEQ ID NO:2 and nucleic acids encoding it have several uses. For example, the specification contemplates "processes for identifying compounds that modulate, i.e., act as agonists or antagonists of, NGPCR expression and/or NGPCR activity. . . . Such compounds can be used as therapeutic agents for the treatment of any of a wide variety of symptoms associated with biological disorders or imbalances." Page 4.

The specification also states that "NGPCR protein, peptide fragments therefrom, mutated, truncated or deleted forms of the NGPCR and/or NGPCR fusion proteins can be prepared for a variety of uses. These uses include but are not limited to the generation of antibodies, as reagents in diagnostic assays, the identification of other

cellular gene products related to the NGPCR, as reagents in assays for screening for compounds that can be used as pharmaceutical reagents useful in the therapeutic treatment of mental, biological, or medical disorders and disease." Page 19.

Finally, the specification discloses that two polymorphic positions were identified in SEQ ID NO:1: position 233 can be either G or A, resulting in either Val or Gly at amino acid 78 of SEQ ID NO:2, and position 316 can be either C or T, resulting in either Arg or Cys at position 106 of SEQ ID NO:2. Page 7.

Discussion

The examiner rejected all of the claims as lacking a disclosed utility sufficient to satisfy 35 U.S.C. § 101.[1] The examiner bears the initial burden of showing that a claimed invention lacks patentable utility. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.").

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. See In re Fisher, 421 F.3d 1365 (Fed. Cir. 2005). The Fisher court interpreted Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility." 421 F.3d at 1370. The Fisher court held that § 101 requires a utility that is both substantial and specific. Id. at 1371. The court held that disclosing a substantial utility means "show[ing] that an invention is useful

[1] The examiner also rejected all of the claims under 35 U.S.C. § 112, first paragraph, for lack of enablement, but that rejection is merely as a corollary of the finding of lack of utility. See the Examiner's Answer, page 6. Therefore, our conclusion with respect to the § 101 issue also applies to the § 112 issue.

to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." Id.

The court held that a specific utility is "a use which is not so vague as to be meaningless." Id. In other words, "in addition to providing a 'substantial' utility, an asserted use must show that that claimed invention can be used to provide a well-defined and particular benefit to the public." Id.

The Fisher court held that none of the uses asserted by the applicant in that case were either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world." Id. at 1373. "Consequently, because Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application, we have no choice to conclude that the claimed ESTs do not have a 'substantial' utility under § 101." Id. at 1374.

"Furthermore, Fisher's seven asserted uses are plainly not 'specific.' Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. . . . Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101." Id.

In this case, the examiner found the specification's disclosure to be inadequate:

> The instant application does not disclose a specific biological role for [the claimed] DNA or the protein encoded thereby or their significance to a particular disease, disorder or physiological process for which they are diagnostic or which one would wish to manipulate for a desired clinical effect.
>
> It is clear from the instant specification that the receptor protein encoded by the isolated nucleic acid described therein is what is termed an "orphan receptor" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this protein and an isolated nucleic acid encoding it may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken Appellant's claimed invention is incomplete.

Examiner's Answer, pages 3-4.

Appellants argue that the claimed nucleic acids encode a protein with a high degree of similarity to known GPCRs and that "[o]f the pharmaceutical products currently being market[ed] by the entire industry, 60% of these drugs target G-protein coupled receptors (Gurrath, 2001, Curr. Med. Chem. 8:1605-1648 . . .). Given that more than half of the currently marketed drugs target proteins that are structurally (7TM proteins) and functionally (G protein interaction) related to the presently described sequences, a preponderance of the evidence clearly weighs in favor of Appellants' assertion that the skilled artisan would readily recognize that the presently described sequences have a specific . . ., credible, and well-established utility." Appeal Brief, pages 11-12.

We do not agree that the characterization of the claimed nucleic acids as encoding G protein-coupled receptors is sufficient to establish their utility. The specification states that "membrane receptor proteins are often involved in transduction pathways that control cell physiology, chemical communication, and gene expression." Page 1. The specification provides no information regarding what biological functions or

activities involve the polypeptide encoded by the instantly claimed nucleic acids, or what ligand binds to the protein of SEQ ID NO:2, or what signal (if any) is transduced by the protein in response to ligand binding.

Thus, the record does not support Appellants' position that the characterization of a polypeptide as a G protein-coupled receptor would have suggested a specific biological function, or any other basis for patentable utility, to a person skilled in the art at the time the application was filed. In the terms used by the Fisher court, such a characterization does not provide a substantial utility because it does not show that the claimed invention is useful as disclosed in its current form, only that it may be useful at some future date after further research: the specification does not disclose a significant and presently available benefit to the public. Cf. Fisher, 421 F.3d at 1371. Mere characterization as a GPCR also fails to provide a specific utility, because it does not "provide a well-defined and particular benefit to the public." Id.

Appellants also argue that "the present nucleotide sequences have utility in assessing gene expression patterns using high-throughput DNA chips" (Appeal Brief, page 12); that they are useful in mapping human chromosomes (id., page 13); and that they can be used to "specifically define that portion of the corresponding genomic locus that actually encodes exon sequence" (id., page 14).

We find that none of these uses meet the requirements of § 101. In this case, as in Fisher, the generic uses asserted by Appellants – assessing gene expression, mapping human chromosomes, and identifying exon sequences – are neither substantial nor specific. Like in Fisher, these uses are "merely hypothetical possibilities, objectives which the claimed [cDNAs], or any [cDNA] for that matter, could possibly achieve, but

none for which they have been used in the real world." Fisher, 421 F.3d at 1373 (emphasis in original). Therefore, they are not substantial utilities.

Nor are they specific utilities, because they could be asserted for any cDNA transcribed from any gene in the human genome. Because nothing about Appellants' asserted utilities sets the claimed nucleic acids apart from any other human cDNA, Appellants have "only disclosed general uses for [the] claimed [cDNAs], not specific ones that satisfy § 101." Id. at 1374.

Finally, Appellants argue that the identified polymorphism in SEQ ID NO:8 makes the nucleic acids useful in "forensic analysis." Appeal Brief, pages 4-6.

We do not agree that the disclosed polymorphism establishes the utility of the claimed nucleic acids. First, Appellants' argument lacks support in the specification or in the evidence of record. The specification discloses the presence of a polymorphism in SEQ ID NO:1 (page 7) but discloses no utilities based on detection of the polymorphism. In particular, the specification does not disclose that the polymorphism is a useful marker for forensic analysis.

In addition, the polymorphism-based utility is neither substantial nor specific. It is not substantial because it is merely a hypothetical possibility, an objective which the disclosed polymorphism, or any polymorphism for that matter, could achieve, but not one for which the claimed nucleic acids have been used in the real world. See Fisher, 421 F.3d at 1373. It is not specific because nothing about the asserted utility sets apart the polymorphism in the claimed nucleic acids from any other polymorphism found in the human genome. See id. at 1374.

Summary

The specification does not disclose a specific and substantial utility for the claimed nucleic acids, as required by 35 U.S.C. § 101. We therefore affirm the examiner's rejection of claims 1-5.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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EG/lbg

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